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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,121	06/25/2003	Eran Harari	02/23511	2219

7590

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

JP

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/603,121		HARARI ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Kathleen Sonnett		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24, drawn to a system for delivery of an implantable device, classified in class 623, subclass 1.23.
  - II. Claims 25-36, drawn to a deployment sleeve, classified in class 623, subclass 1.28.
  - III. Claims 37-49, drawn to another system for delivery of an implantable device, classified in class 623, subclass 1.12.
  - IV. Claims 50-57, drawn to a device for introducing into the body, classified in class 604, subclass 164.13.
  - V. Claims 58-64, drawn to a method of positioning implantable device in body lumen, classified in class 604, subclass 508.
  - VI. Claims 65-67, drawn to method for preventing entanglement of implantable device within delivery system, classified in class 128, subclass 887.
  - VII. Claims 68-71, drawn to a method of positioning an implantable device within a delivery system, classified in class 604, subclass 23.64.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does

not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the outer tube does not require longitudinal ridges. The subcombination has separate utility such as the deployment sleeve can be put over an inner tube without an intermediate tube between the sleeve and inner tube. Alternatively, the sleeve itself can be used for drug delivery without any other tubes.

3. Inventions III and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require that the intermediate tube be comprised of a material to ease sliding of the outer tube. The subcombination has separate utility such as it can be used without a stopper attached to the inner tube.

4. Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the

particulars of the subcombination as claimed because the combination can be used with an inner tube that does not have an ellipsoidal shaped tip. The subcombination has separate utility such as the elongated member can be used alone in surgery without any tubes or with a single tube (without an intermediate tubing that eases sliding).

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be used with a system in which the intermediate tube is not made of a material that eases sliding of the outer tube. Conversely, it may employ a roughened intermediate tube in the case where accidental slipping needs to be avoided and it is desirable to have to exert a substantial pressure on the device to move the tubes relative to each other.

6. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be used with a system in which the intermediate tube is not made of a material that eases sliding of the outer tube. Conversely, it may employ a roughened intermediate tube in the case where accidental slipping needs to be avoided and it is desirable to

have to exert a substantial pressure on the device to move the tubes relative to each other.

7. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a method that does not require providing a sleeve with indentations. Alternatively, the method can be practiced with an implantable device that has no intermediate tube.

8. Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the outer tube does not require longitudinal ridges. The subcombination has separate utility such as the deployment sleeve can be put over an inner tube without an intermediate tube between the sleeve and inner tube. Alternatively, the sleeve itself can be used for drug delivery without any other tubes.

9. Inventions II and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in

scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as the sleeve can be used to introduce another hollow catheter without an elongated member with an ellipsoidal-shaped tip or it can be used to deliver drugs. See MPEP § 806.05(d).

10. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be used with an outer tube that does not have longitudinal ridges. Alternatively, the product can be used for drug delivery or with only one other tube.

11. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be used with an outer tube that does not have longitudinal ridges. Alternatively, the product can be used for drug delivery or with only one other tube.

12. Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be used with a sleeve that does not have ridges along the longitudinal axis.

Alternatively, the product can be used without an implantable device at least partially on the sleeve.

13. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the inner tube does not require an ellipsoidal-shaped tip. The subcombination has separate utility such as the elongated member can be used alone or in any catheter system such as one with no intermediate tube.

14. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be practiced with a delivery device that does not include a stopper attached to an inner tube.

15. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a process that does not involve a diverter positioned on the inner tube. The product may be used to deliver a different implantable device such as suture or a stent.

16. Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a method that does not require the use of a sleeve on the distal end of the inner tube. Alternatively, the method can be practiced with a device which does not have a stopper attached to the inner tube.

17. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a method that does not include an intermediate or outer tube; that is, it

can be used alone during surgery in which tissue can be accessed through an open wound. Alternatively, the method can be practiced with an inner tube that does not have an ellipsoidal-shaped tip.

18. Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a method that does not include an intermediate or outer tube; that is, it can be used alone during surgery in which tissue can be accessed through an open wound. Alternatively, the method can be practiced with an inner tube that does not have an ellipsoidal-shaped tip.

19. Inventions IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case In the instant case the product can be used in a method that does not include an intermediate or outer tube; that is, it can be used alone during surgery in which tissue can be accessed through an open wound. Alternatively, the method can be practiced with an inner tube that does not have an ellipsoidal-shaped tip.

20. Inventions V and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination V has separate utility such as the method can be used to implant a device within a body lumen that does not require providing a delivery system that has a diverter positioned on the inner tube. See MPEP § 806.05(d).

21. Inventions V and VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination V has separate utility such as the method can be used to implant a device within a body lumen that does not require the step of providing a sleeve with indentations on a distal end of an inner tube. See MPEP § 806.05(d).

22. Inventions VI and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the method can be practiced without a sleeve that has indentations. The subcombination has separate utility such as the method can be used for positioning an implantable device within a delivery system

that does not require the step of providing a stopper or diverter placed on the end of an inner tube.

23. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

24. Due to the complexity of the restriction, a telephone call was not made to request an oral election to the above restriction requirement.

25. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

26. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

27. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

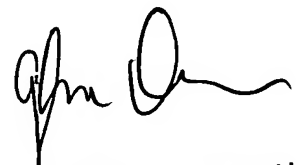
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS  
6/21/2006

  
GLENN K. DAWSON  
PRIMARY EXAMINER